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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,099

04/09/2008

Claus Harder

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25207 7590 02/24/2010  
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EXAMINER

BUMGARNER, MELBA N

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

02/24/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-at@btlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,099	<b>Applicant(s)</b> HARDER ET AL.	
	<b>Examiner</b> Melba Bumgarner	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/18/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 13 is objected to because of the following informalities: in line 2, it appears that “for” was inadvertently deleted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (5,824,049). Ragheb et al. disclose an implant for releasing an active substance into a vessel through which a body medium flows (column 3 line 12), the implant 10 comprising a basic body 12 comprising a biodegradable material as substrate 14 for the active substance 18 to be released, and around which the body medium flows on the inside and/or outside. As to claim 2, the basic body comprises at least in part a biodegradable material of tungsten alloy (column 7 line 36). As to claim 11, the basic body is cylindrical. Although significant patentable weight is not given to the intended use of the implant, Ragheb et al. disclose the implant providing regional drug delivery (column 5 line 60) and used for tumour treatment (column 8 line 45).

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4. Claims 1, 2, and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Momma et al. (2005/0027350). Momma et al. disclose an implant for releasing an active substance into a vessel through which a body medium flows ([0012] line 2), the implant ([0035] line 5) comprising a basic body comprising a biodegradable material of magnesium alloy as substrate ([0035] line 8) for the active substance ([0041] line 1) to be released, and around which the body medium flows on the inside and/or outside. Momma et al. show the basic body of the implant comprises a first, non-expanded condition and a second, expanded condition in that the implant (stent) is described as expandable type ([0024] line 4). Momma et al. disclose an embodiment having the basic body comprising a coating 62 on at least certain regions on its sides facing the vessel, at least one cavity (within 40), and at least one hollow body (within 38), which contain the active substance; and the basic body is tubular.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Meyer-Lindenberg et al. (WO02/100452). Ragheb et al. disclose an implant that shows the limitations as described above; however, they do not show specific alloy or composition of alloy. Meyer-Lindenberg teach a degradable implant comprising magnesium alloys among which includes 0.01 to 7 mass percent lithium, 0.01 to 16 mass percent aluminum, 0.01 to 7 mass percent yttrium, 0.01 to 8 mass percent rare earth metals, and balance of

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magnesium (page 4 line 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Ragheb et al. to comprise the alloy of Meyer-Lindenberg in order to provide an alloy with improved degradation and reduced gas pocket formation. Meyer-Lindenberg teach alloy comprising yttrium and rare earth metal. It would have been obvious to one of ordinary skill in the art as to specifically having alloy of WE43. Meyer-Lindenberg also teach magnesium alloy comprising least amount of zirconium (page 11 line 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made as to the range of percentage of zirconium, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

7. Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Momma et al. in view of Meyer-Lindenberg et al. Momma et al. disclose an implant that shows the limitations as described above; however, they do not show specific alloy or composition of alloy. Meyer-Lindenberg teach a degradable implant comprising magnesium alloys among which includes 0.01 to 7 mass percent lithium, 0.01 to 16 mass percent aluminum, 0.01 to 7 mass percent yttrium, 0.01 to 8 mass percent rare earth metals, and balance of magnesium (page 4 line 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Momma et al. to comprise the alloy of Meyer-Lindenberg in order to provide an alloy with improved degradation and reduced gas pocket formation. Meyer-Lindenberg teach alloy comprising yttrium and rare earth metal. It would have been obvious to one of ordinary skill in the art as to specifically having alloy of WE43. Meyer-Lindenberg also teach magnesium alloy comprising least amount of zirconium (page 11 line 19). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made as to the range of percentage of zirconium, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is (571)272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melba Bumgarner/  
Primary Examiner, Art Unit 3767